Holistic Outcomes from the COMFORT PNS RCT

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INTRODUCTION

In recent years, holistic outcomes are being used in an attempt to present a more comprehensive assessment of the effectiveness of a device in treating chronic, intractable pain[1]. These composite endpoints are a combination of pain relief and one or more functional outcomes like activities of daily living, mood, sleep, quality of life and impression of change. The COMFORT PNS RCT (Peripheral Nerve Stimulation; Randomized Controlled Trial) is an ongoing study to document the effectiveness and safety of a PNS system with a micro-Implantable Pulse Generator (micro-IPG, Nalu Medical, Inc. Carlsbad, CA).

METHODS

The COMFORT study is a post-market, open-label, minimal risk RCT, ongoing at 14 pain management centers in the USA. The study was approved by the Institutional Review Board and in compliance with required regulations. Subjects who are eligible, consented, and prescribed PNS therapy to treat chronic pain in the shoulder, knee, low back and foot will be considered for study participation. Subjects in the active arm, completing a successful trial were implanted with the permanent device and followed out to 36 months from device activation. Subjects in the control arm were followed at same time points and eligible to cross-over at 3-months.

Patient reported outcomes (PRO) were captured and screened for responders based upon Minimal Clinically Important Difference (MCID). These MCIDs were defined based upon the literature, as follows: NRS pain scores (50% reduction[1]), Patient Global Impression of Change (PGIC; Much, very much or minimally improved[1]), Oswestry Disability Index (ODI; 10-point change[2]). This MCID was used to evaluate the composite outcomes at the 3-month endpoint.

REFERENCES

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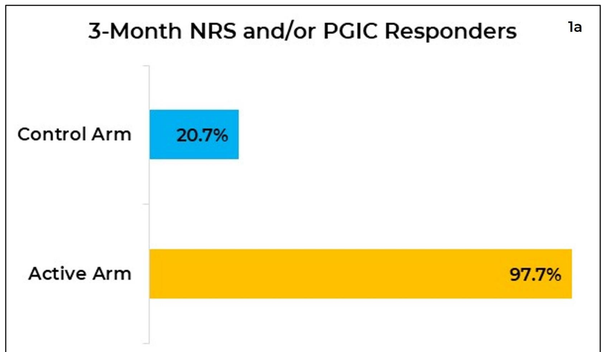
RESULTS

To date, 89 subjects have been randomized in the study; of these, 72 (43 in Active Arm and 29 in Control Arm) subjects have completed the 3-month visit. Composite outcomes that linked NRS pain scores to PGIC showed that 97.7% (42/43) of the active arm subjects and 21% (6/29) of control arm subjects achieved the above defined MCID for both or one of the outcomes (Figure 1a). Similarly, outcomes that linked NRS pain scores to ODI showed that 93% (40/43) of the active arm subjects and 34.5% (10/29) of the control arm subjects achieved the above defined MCID in one or both the outcome measures (Figure 1b).



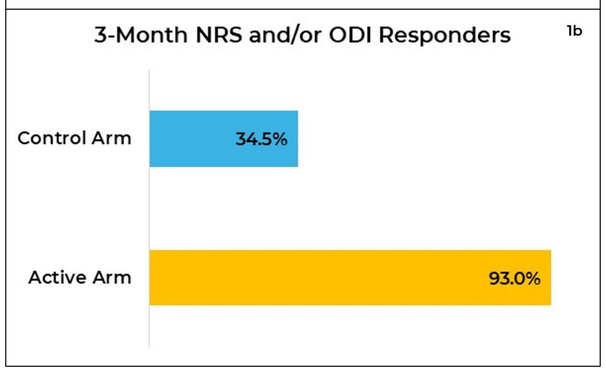
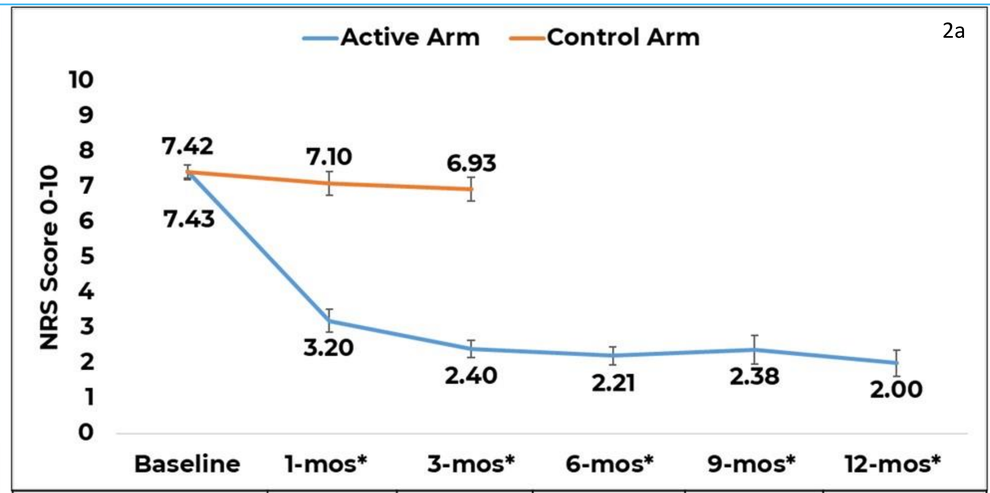
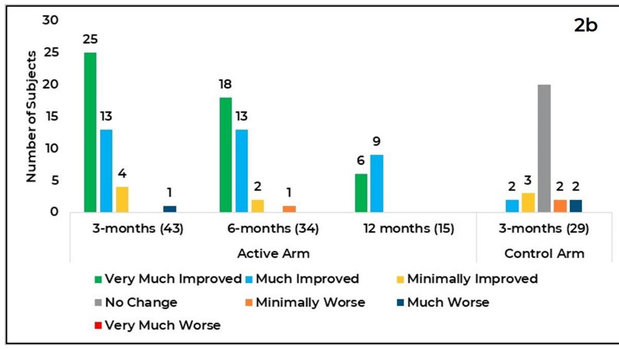


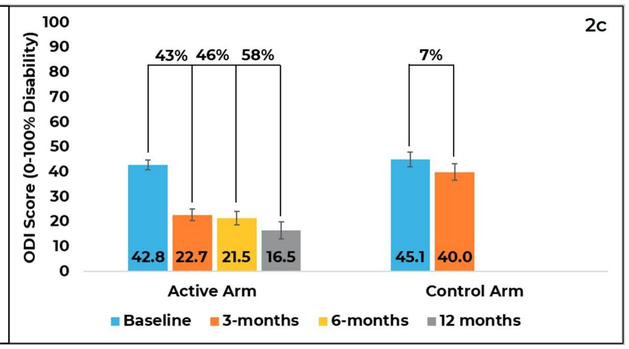
***Figure 1a**. Composite outcomes combining NRS and/or PGIC.*
***Figure 1b.** Composite outcomes combining NRS and/or ODI.*



Active Arm*	n=45	n=43	n=34	n=21	n=15
Responder Rate	76%	84%	88%	71%	87%
% Pain Relief	57%	67%	70%	68%	73%
Control Arm	n=31	n=29	*p<0.001		
Responder Rate	10%	3%			
% Pain Relief	4%	6%			

***Figure 2a**. NRS pain outcomes in the Active and Control Arms with Responder Rates and % Relief, from baseline to 1-year. Responder rate of 84% recorded at 3-months (primary endpoint), with a statistically significant (p<0.001) difference between the 2 arms.*
***Figure 2b**. PGIC outcomes in Active and Control Arms.*
***Figure 2c.** ODI change in both arms from baseline to 1-year. 43% of subjects in the Active Arm showed improvement in ODI at 3-months compared to 7% of subjects in the Control Arm (p<0.001). 58% subjects showed improvement at 1-year.*





CONCLUSION

Holistic outcomes allow for a more comprehensive assessment of patient outcomes to therapy. These results are consistent with reports on improvements in pain, PGIC, ODI and other functional outcomes in this study[3].